APPENDIX A

UNITED STATES COURT OF APPEALS
FEDERAL CIRCUIT

Nos. 93-1503 to 93-1505

BURROUGHS WELLCOME CO.,
Plaintiff-Appellee,

v.

BARR LABORATORIES, INC.,
Defendant-Appellant,

and

NOVOPHARM, INC. and NOVOPHARM, LTD.,
Defendants-Appellants.

Nov. 22, 1994

Rehearing Denied Dec. 15, 1994

Before MAYER, LOURIE, and SCHALL, Circuit Judges.

MAYER, Circuit Judge.

Barr Laboratories, Inc., Novopharm, Inc., and Novopharm, Ltd., appeal the order of the United States District Court for the Eastern District of North Carolina, *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 828 F.Supp. 1208 (E.D.N.C.1993), granting the motion of Burroughs Wellcome Co. for judgment as a matter of law that six United States patents were not invalid and were infringed. We affirm in part, vacate in part, and remand.

Background

Burroughs Wellcome Co. is the owner of six United States patents that cover various preparations of 3'-azidothymidine (AZT) and methods for using that drug in the treatment of persons infected with the human immunodeficiency virus (HIV).[1] Each of these patents names the same five inventors—Janet Rideout, David Barry, Sandra Lehrman, Martha St. Clair, and Phillip Furman (Burroughs Wellcome inventors)—all of whom were employed by Burroughs Wellcome at the time the inventions were alleged to have been conceived. The defendants-appellants concede that all five are properly named as inventors on the patents.

Burroughs Wellcome's patents arise from the same parent application filed on September 17, 1985.[2] Five of the patents relate to the use of AZT to treat patients infected with HIV or who have acquired immunodeficiency syndrome (AIDS).[3] The other patent, the '750 patent, covers

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[1] Although two of the patents claim pharmaceutical compositions of AZT, not methods of treatment per se, the parties treat all of the patents as covering the particular use of AZT as a treatment for AIDS and its symptoms. The district court adopted this interpretation and applied the patents as though all claimed methods of treatment; no party argues for another interpretation, so we do the same.

[2] The following patents are at issue: U.S. Patent No. 4,724,232 (the '232 patent), filed September 17, 1985, issued February 9, 1988; No. 4,828,838 (the '838 patent), filed October 21, 1987, issued May 9, 1989; No. 4,833,130 (the '130 patent), filed October 20, 1987, issued May 23, 1989; No. 4,837,208 (the '208 patent), filed October 20, 1987, issued June 6, 1989; No. 4,818,538 (the '538 patent), filed October 21, 1987, issued April 4, 1989; and No. 4,818,750 (the '750 patent), filed October 20, 1987, issued April 4, 1989.

[3] Claim 1 of the '232 patent covers "[a] method of treating a human having acquired immunodeficiency syndrome comprising the oral administration of an effective acquired immunodeficiency syn-

a method of using AZT to increase the T-lymphocyte count of persons infected with HIV.[4]

In the early 1980s, scientists began to see patients with symptoms of an unknown disease of the immune system, now known as AIDS. The disease attacks and destroys certain white blood cells known as CD4 T-lymphocytes or T-cells, which form an important component of the body's immune system. The level of destruction eventually becomes so great that the immune system is no longer able to mount an effective response to infections that pose little threat to a healthy person.

In mid-1984, scientists discovered that AIDS was caused by a retrovirus, known as HTLV III or, more commonly today, HIV. After the identification of HIV, Burroughs Wellcome began to search for a cure, screening compounds for antiretroviral activity using two murine

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drome treatment amount of 3'-azido-3'-deoxythymidine to said human."

Claim 1 of the '838 patent covers "[a] pharmaceutical preparation comprising a capsule containing 5 to 500 mg of 3'-azido-3'-deoxythymidine."

Claim 1 of the '130 patent covers "[a] method of treating a human having an HTLV III virus infection comprising administering to said human an effective HTLV III virus treatment amount of 3'-azido-3'-deoxythymidine."

Claim 1 of the '208 patent covers "[a] method of treating a human having antibodies to the HTLV III virus which comprises administering to said human an effective HTLV III treatment amount of 3'-azido-3'-deoxythymidine."

Claim 1 of the '538 patent covers "[a] sealed container including a pharmaceutical composition in unit dosage form comprising 5 to 500 mg of 3'-azido-3'-deoxythymidine together with a pharmaceutically acceptable solid carrier."

[4] Claim 1 of the '750 patent covers "[a] method of increasing the number of T-lymphocytes in a human infected with the HTLV III virus comprising administering to said human an effective amount of 3'-azido-3'-deoxythymidine or a pharmaceutically acceptable alkali metal, alkaline earth or ammonium salt thereof."

(or mouse) retroviruses, the Friend leukemia virus and the Harvey sarcoma virus.

At about this time, scientists at the National Institutes of Health (NIH), led by Samuel Broder, were looking for effective AIDS therapies as well. Unlike Burroughs Wellcome, Broder and his colleagues used live HIV, and were able to develop a test that could demonstrate a compound's effectiveness against HIV in humans using a unique line of T-cell clones (the ATH8 cell line). The NIH scientists began to seek compounds from private pharmaceutical companies for screening in their cell line. After Burroughs Wellcome contacted Broder in the fall of 1984, he agreed to accept compounds from Burroughs Wellcome under code for testing against live HIV.

Burroughs Wellcome's Rideout selected AZT and a number of other compounds for testing in the murine screens on October 29, 1984. The tests, performed at Burroughs Wellcome facilities by St. Clair, showed that AZT had significant activity against both murine retroviruses at low concentrations. In light of these positive results, the Burroughs Wellcome inventors met on December 5, 1984, to discuss patenting the use of AZT in the treatment of AIDS. Burroughs Wellcome's patent committee thereafter recommended that the company prepare a patent application for future filing. By February 6, 1985, the company had prepared a draft application for filing in the United Kingdom. The draft disclosed using AZT to treat patients infected with HIV, and set out various pharmaceutical formulations of the compound in an effective dosage range to treat HIV infection.

Two days earlier, on February 4, 1985, Burroughs Wellcome had sent a sample of AZT, identified only as Compound S, to Broder at NIH. In an accompanying letter, Lehrman told Broder of the results of the murine retrovirus tests and asked that he screen the compound for activity against HIV in the ATH8 cell line. Another NIH scientist, Hiroaka Mitsuya, performed the test in

mid-February 1985, and found that Compound S was active against HIV. Broder informed Lehrman of the results by telephone on February 20, 1985. Burroughs Wellcome filed its patent application in the United Kingdom on March 16, 1985.

After Burroughs Wellcome learned that AZT was active against HIV, it began the process of obtaining Food and Drug Administration (FDA) approval for AZT as an AIDS therapy. As a part of the clinical trials leading to FDA approval, Broder and another NIH scientist, Robert Yarchoan, conducted a Phase I human patient study which showed that treatment with AZT could result in an increase in the patient's T-cell count. Broder reported this result to Lehrman on July 23, 1985. In 1987, the FDA approved AZT for marketing by Burroughs Wellcome; Burroughs Wellcome markets the drug for treatment of HIV infection under the trademark Retrovir.

On March 19, 1991, Barr Laboratories, Inc. (Barr) sought FDA approval to manufacture and market a generic version of AZT by filing an Abbreviated New Drug Application (ANDA) pursuant to 21 U.S.C. § 355(j) (1988). As part of the process, Barr certified to the FDA that Burroughs Wellcome's patents were invalid or were not infringed by the product described in its ANDA. After Barr informed Burroughs Wellcome of its action, Burroughs Wellcome commenced this case for patent infringement against Barr on May 14, 1991, alleging technical infringement of its patents under 35 U.S.C. § 271(e)(2)(A) (1988).

Barr filed a counterclaim under 35 U.S.C. § 256 (1988) seeking correction of the patents to list Broder and Mitsuya as coinventors. Barr admitted that its AZT product would infringe the patents, but contended that it did not because Barr had obtained a license to manufacture and sell AZT from the government, which should be deemed the owner of the interest of coinventors Broder and Mitsuya in the AZT patents. Burroughs Wellcome

denied that Broder and Mitsuya were coinventors and also responded that the assertion of any rights of Broder, Mitsuya, or the government in the patents was barred by laches, estoppel, and waiver.

Thereafter, Novopharm, Ltd. filed an ANDA of its own, seeking approval to manufacture and market its generic version of AZT. Burroughs Wellcome filed infringement suits against Novopharm, Ltd. and its American subsidiary Novopharm, Inc., which were consolidated with the suit against Barr.[5] Like Barr, Novopharm, Ltd. admitted that its AZT product would infringe the claims of the six patents, but for the failure of Burroughs Wellcome to name the NIH scientists as coinventors of the subject matter of the patents. Although Novopharm, Inc., agreed to be bound by any injunction issued against its parent, it argued that it had not infringed the patents because it had not filed an ANDA and had no AZT product of its own.[6] Novopharm contended that Broder and Mitsuya should have been named as inventors on five of the patents, and contended that Broder and Yarchoan were coinventors of the '750 patent. It maintained that the patents were invalid because of the alleged nonjoinder, and because Burroughs Wellcome had omitted the coinventors with deceptive intent, the patents were unenforceable for inequitable conduct.

After more than three weeks of trial, while Burroughs Wellcome was still in the process of presenting its case,

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[5] Novopharm, Inc. and Novopharm, Ltd. are jointly represented by counsel and make many of the same arguments on appeal. Except where it is more appropriate to refer to them individually, we will refer to them together as Novopharm.

[6] Burroughs Wellcome alleges that Novopharm, Inc. is liable for the infringement by Novopharm, Ltd. on grounds that it participated in or induced Novopharm, Ltd.'s infringing activities. But Burroughs Wellcome had the burden of proving infringement by Novopharm, Inc. and on the record before us there is simply no evidence to support a conclusion on this factual question. The judgment against Novopharm, Inc. is vacated.

the district court granted Burroughs Wellcome's motion for judgment as a matter of law against all of the defendants, concluding that the Burroughs Wellcome inventors had conceived of the subject matter of the inventions at some time before February 6, 1985, without the assistance of Broder, Mitsuya, or Yarchoan. The court rejected the arguments of Barr and Novopharm that they should be allowed to present evidence that the Burroughs Wellcome inventors had no reasonable belief that the inventions would actually work—that AZT was in fact active against HIV—until they were told the results of the NIH testing.

The court also rejected Novopharm's argument that the Burroughs Wellcome inventors had not conceived the invention of the '750 patent—the use of AZT to increase a patient's T-cell count—before July 23, 1985, when Broder reported the results of the NIH patient study to Lehrman. The court concluded that the increase in T-cell count was an obvious phenomenon known to the inventors that would result from administration of AZT. And the district court denied Barr's renewed motion for partial summary judgment on Burroughs Wellcome's equitable defenses to its counterclaim for correction of the patents under section 256.

Discussion

The arguments of both Barr and Novopharm are directed to when the inventors conceived the invention. Burroughs Wellcome says it was before they learned the results of the NIH tests; Barr and Novopharm say that confirmation of the inventions' operability, which came from the NIH tests, was an essential part of the inventive process. If Burroughs Wellcome is right, then the patents name the proper inventors, they are not invalid, and the appellants are liable for infringement. If Barr and Novopharm are correct, then Broder, Mitsuya, and Yarchoan should have been named as joint inventors and the resolution of Burroughs Wellcome's infringement suits is premature.

The district court's grant of judgment as a matter of law under Rule 50(a) is subject to de novo review. *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 821, 23 USPQ2d 1426, 1431 (Fed.Cir.1992). We must apply the same standard as did that court, examining the record in the light most favorable to the nonmovant and drawing inferences in that party's favor. We may affirm only if the judgment entered was the only one possible under the controlling law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250, 106 S.Ct. 2505, 2511, 91 L.Ed.2d 202 (1986).

A joint invention is the product of a collaboration between two or more persons working together to solve the problem addressed. 35 U.S.C. § 116 (1988); *Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co.*, 973 F.2d 911, 917, 23 USPQ2d 1921, 1926 (Fed.Cir.1992). People may be joint inventors even though they do not physically work on the invention together or at the same time, and even though each does not make the same type or amount of contribution. 35 U.S.C. § 116. The statute does not set forth the minimum quality or quantity of contribution required for joint inventorship.

Conception is the touchstone of inventorship, the completion of the mental part of invention. *Sewall v. Walters*, 21 F.3d 411, 415, 30 USPQ2d 1356, 1359 (Fed.Cir. 1994). It is "the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376, 231 USPQ 81, 87 (Fed.Cir.1986) (citation omitted). Conception is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation. *Sewall*, 21 F.3d at 415, 30 USPQ2d at 1359; *see also Coleman v. Dines*, 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed.Cir.1985) (conception must include every feature of claimed invention). Because it is a mental act,

courts require corroborating evidence of a contemporaneous disclosure that would enable one skilled in the art to make the invention. *Coleman v. Dines*, 754 F.2d at 359, 224 USPQ at 862.

Thus, the test for conception is whether the inventor had an idea that was definite and permanent enough that one skilled in the art could understand the invention; the inventor must prove his conception by corroborating evidence, preferably by showing a contemporaneous disclosure. An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue. *See Fiers v. Revel*, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1605 (Fed.Cir. 1993); *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed.Cir. 1991) (no conception of chemical compound based solely on its biological activity). The conception analysis necessarily turns on the inventor's ability to describe his invention with particularity. Until he can do so, he cannot prove possession of the complete mental picture of the invention. These rules ensure that patent rights attach only when an idea is so far developed that the inventor can point to a definite, particular invention.

But an inventor need not know that his invention will work for conception to be complete. *Applegate v. Scherer*, 332 F.2d 571, 573, 141 USPQ 796, 799 (CCPA 1964). He need only show that he had the idea; the discovery that an invention actually works is part of its reduction to practice. *Id.; see also Oka v. Youssefyeh*, 849 F.2d 581, 584 n. 1, 7 USPQ2d 1169, 1171 n. 1 (Fed.Cir.1988).

Barr and Novopharm suggest that the inventor's definite and permanent idea must include a reasonable expectation that the invention will work for its intended purpose. They argue that this expectation is of paramount importance when the invention deals with uncer-

tain or experimental disciplines, where the inventor cannot reasonably believe an idea will be operable until some result supports that conclusion. Without some experimental confirmation, they suggest, the inventor has only a hope or an expectation, and has not yet conceived the invention in sufficiently definite and permanent form. But this is not the law. An inventor's belief that his invention will work or his reasons for choosing a particular approach are irrelevant to conception. *MacMillan v. Moffett*, 432 F.2d 1237, 1239, 167 USPQ 550, 552 (CCPA 1970).

To support their reasonable expectation rule, Barr and Novopharm point to a line of cases starting with *Smith v. Bousquet*, 111 F.2d 157, 45 USPQ 347 (CCPA 1940), establishing the so-called doctrine of simultaneous conception and reduction to practice.[7] *Smith* was an interference priority contest between alleged inventors of the use of two known compounds as insecticides. Both parties asserted priority based on testing of the compounds against selected insect species. Noting the unpredictability of the experimental sciences of chemistry and biology, in particular the uncertain relationship between chemical structure and biological activity, *Smith* declined to find conception until the invention had been reduced to practice by the filing of the first patent application. *Id.* at 162, 45 USPQ at 352. Barr and Novopharm read this and subsequent cases to establish, or at least support, their rule that conception of an invention in an unpredictable field occurs only when the inventor has reasonable grounds to believe the invention will work.

But these cases do not stand for the proposition that an inventor can never conceive an invention in an unpre-

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[7] Barr and Novopharm also point to dictum in *Biel v. Chessin*, 347 F.2d 898, 146 USPQ 293 (CCPA 1965), suggesting that conception of a method of treating the human body requires a reasonable understanding that the method will work for its intended purpose. No court has applied this dictum as controlling, and we decline to do so here.

dictable or experimental field until reduction to practice. In rejecting the asserted evidence of conception, *Smith* said as to one of the compounds:

> it is apparent from the record that neither [party] had in mind at the time the suggestions were originally made, nor at any time thereafter, until successful tests, if any, were made, what insects, if any, it might be effective against, or how it might be applied to produce the desired results. Accordingly, neither party had a definite idea of the "complete and operative invention" here involved prior to a successful reduction—actual or constructive—of it to practice.

Id. Thus, in awarding priority to Smith based on his constructive reduction to practice, the court relied not on the inherent unpredictability of the science, but on the absence of any evidence to corroborate an earlier conception for either of the parties.

It is undoubtedly true that "[i]n some instances, an inventor is unable to establish a conception until he has reduced the invention to practice through a successful experiment." *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021; *Alpert v. Slatin*, 305 F.2d 891, 894, 134 USPQ 296, 299 (CCPA 1962) (no conception "where results at each step do not follow as anticipated, but are achieved empirically by what amounts to trial and error"). But in such cases, it is not merely because the field is unpredictable; the alleged conception fails because, as in *Smith*, it is incomplete. Then the event of reduction to practice in effect provides the only evidence to corroborate conception of the invention.

Under these circumstances, the reduction to practice can be the most definitive corroboration of conception, for where the idea is in constant flux, it is not definite and permanent. A conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines

the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice. *See Amgen*, 927 F.2d at 1207, 18 USPQ2d at 1021 (no conception until reduction to practice where others tried and failed to clone gene using suggested strategy); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1387, 181 USPQ 453, 457-58 (CCPA 1974) (focusing on nature of subsequent research as indicator that inventors encountered no perplexing intricate difficulties). It is this factual uncertainty, not the general uncertainty surrounding experimental sciences, that bears on the problem of conception.

Barr and Novopharm argue for a broader reading of *Amgen* and *Fiers* in support of their reasonable expectation rule. Both of these cases involve conception of a DNA encoding a human protein—a chemical compound. Conception of a chemical substance includes knowledge of both the specific chemical structure of the compound and an operative method of making it. *Fiers*, 984 F.2d at 1169, 25 USPQ2d at 1604; *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021; *Oka*, 849 F.2d at 583, 7 USPQ2d at 1171. The alleged inventors in *Fiers* and *Amgen* claimed conception of their respective inventions before they knew relevant chemical structure—the nucleotide sequence—so the courts found no conception until experimentation finally revealed that structure. Here, though, Burroughs Wellcome's inventions use a compound of known structure; the method of making the compound is also well known.

We emphasize that we do not hold that a person is precluded from being a joint inventor simply because his contribution to a collaborative effort is experimental. Instead, the qualitative contribution of each collaborator is the key—each inventor must contribute to the joint arrival at a definite and permanent idea of the invention as it will be used in practice.

Nor do we suggest that a bare idea is all that conception requires. The idea must be definite and permanent in the sense that it involves a specific approach to the particular problem at hand. It must also be sufficiently precise that a skilled artisan could carry out the invention without undue experimentation. And, of course, the alleged conception must be supported by corroborating evidence. On the facts before us, it is apparent that the district court correctly ruled against Barr and Novopharm as to five of the patents, but that the court's judgment as to the sixth, the '750 patent, was premature.

The '232, '838, '130, '208, and '538 patents encompass compositions and methods of using AZT to treat AIDS. The Burroughs Wellcome inventors claim conception of these inventions prior to the NIH experiments, based on the draft British patent application. That document is not itself a conception, for conception occurs in the inventors' minds, not on paper. The draft simply corroborates the claim that they had formulated a definite and permanent idea of the inventions by the time it was prepared.

The Burroughs Wellcome inventors set out with the general goal of finding a method to treat AIDS, but by the time Broder confirmed that AZT was active against HIV, they had more than a general hope or expectation. They had thought of the particular antiviral agent with which they intended to address the problem, and had formulated the idea of the inventions to the point that they could express it clearly in the form of a draft patent application, which Barr and Novopharm concede would teach one skilled in the art to practice the inventions. The draft expressly discloses the intended use of AZT to treat AIDS. It sets out the compound's structure, which, along with at least one method of preparation, was already well known. The draft also discloses in detail both how to prepare a pharmaceutical formulation

of AZT and how to use it to treat a patient infected with HIV. The listed dosages, dose forms, and routes of administration conform to those eventually approved by the FDA. The draft shows that the idea was clearly defined in the inventors' minds; all that remained was to reduce it to practice—to confirm its operability and bring it to market. *See Haskell v. Colebourne*, 671 F.2d 1362, 1365-66, 213 USPQ 192, 194 (CCPA 1982) (enabling draft patent application sufficient to corroborate conception).

An examination of the events that followed the preparation of Burroughs Wellcome's draft confirms the soundness of the conception. Broder and Mitsuya received from Burroughs Wellcome a group of compounds, known to Broder and Mitsuya only by code names, selected for testing by the Burroughs Wellcome inventors. They then tested those compounds for activity against HIV in their patented cell line. The test results revealed for the first time that one of the compounds, later revealed to be AZT, was exceptionally active against the virus.

Here, though, the testing was brief, simply confirming the operability of what the draft application disclosed. True, the science surrounding HIV and AIDS was unpredictable and highly experimental at the time the Burroughs Wellcome scientists made the inventions. But what matters for conception is whether the inventors had a definite and permanent idea of the operative inventions. In this case, no prolonged period of extensive research, experiments, and modification followed the alleged conception. By all accounts, what followed was simply the normal course of clinical trials that mark the path of any drug to the marketplace.

That is not to say, however, that the NIH scientists merely acted as a "pair of hands" for the Burroughs Wellcome inventors. Broder and Mitsuya exercised considerable skill in conducting the tests, using their patented

cell line to model the responses of human cells infected with HIV. Lehrman did suggest initial concentrations to Broder, but she hardly controlled the conduct of the testing, which necessarily involved interpretation of results for which Broder and Mitsuya, and very few others, were uniquely qualified. But because the testing confirmed the operability of the inventions, it showed that the Burroughs Wellcome inventors had a definite and permanent idea of the inventions. It was part of the reduction to practice and inured to the benefit of Burroughs Wellcome.

Barr and Novopharm allege error in the district court's refusal to hear their evidence of the poor predictive value of the murine retrovirus screens for activity against HIV. Regardless of the predictive value of the murine tests, however, the record shows that soon after those tests, the inventors determined, for whatever reason, to use AZT as a treatment for AIDS, and they prepared a draft patent application that specifically set out the inventions, including an enabling disclosure. Obviously, enablement and conception are distinct issues, and one need not necessarily meet the enablement standard of 35 U.S.C. § 112 to prove conception. *See Fiers*, 984 F.2d at 1169, 25 USPQ2d at 1605. But the enabling disclosure does suffice in this case to confirm that the inventors had concluded the mental part of the inventive process—that they had arrived at the final, definite idea of their inventions, leaving only the task of reduction to practice to bring the inventions to fruition.

The question is not whether Burroughs Wellcome reasonably believed that the inventions would work for their intended purpose, the focus of the evidence offered by Barr and Novopharm, but whether the inventors had formed the idea of their use for that purpose in sufficiently final form that only the exercise of ordinary skill remained to reduce it to practice. *See MacMillan v. Moffett*, 432 F.2d at 1239, 167 USPQ at 552 (Inventor's "reasons or

lack of reasons for including U-5008 are not relevant to the question of conception. The important thing is that he did think in definite terms of the method claimed."). Whether or not Burroughs Wellcome believed the inventions would in fact work based on the mouse screens is irrelevant.

We do not know precisely when the inventors conceived their inventions, but the record shows that they had done so by the time they prepared the draft patent application that thoroughly and particularly set out the inventions as they would later be used. The district court correctly ruled that on this record, the NIH scientists were not joint inventors of these inventions.

The '750 patent is another question. It claims "[a] method of increasing the number of T-lymphocytes in a human infected with the [HIV] virus comprising administering to said human an effective amount of" AZT. Novopharm argues that there is no evidence, under any test of inventorship, that the Burroughs Wellcome inventors conceived of this invention until after the Phase I patient study conducted by Broder and Yarchoan revealed that AZT could lead to increased levels of T-cells in AIDS patients.

Novopharm is right that the record is devoid of any statement that the inventors thought AZT could raise a patient's T-cell levels, but evidence need not always expressly show possession of the invention to corroborate conception. The district court held that the record supported conception as a matter of law, concluding that "an increase in T-lymphocyte count was an 'obvious,' natural phenomenon known to the [Burroughs Wellcome] inventors that would result from the inhibition of a retrovirus." *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 828 F.Supp. at 1213. Burroughs Wellcome argues that this conclusion was proper because increased T-cell count is simply an obvious property or use of the greater discovery at issue here, the treatment of HIV infection with AZT. Because

an increase in T-lymphocytes follows inevitably from treatment of AIDS patients with AZT, Burroughs Wellcome says, Broder and Yarchoan merely observed that the method invented by the Burroughs Wellcome inventors had qualities that the inventors failed to perceive. Burroughs Wellcome says this is not an inventive contribution to the claims of any of the AZT patents.

But even though all six patents arise from the same parent application and are subject to terminal disclaimers to avoid rejection for obviousness-type double patenting, each patent claims a different invention.[8] *See In re Longi*, 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed.Cir.1985) (inventor can get only one patent for any single invention). It is true that the Patent Office determined that the method of the '750 patent would have been obvious to those skilled in the art in light of the inventions claimed in the other patents. That is, however, irrelevant to the question whether the Burroughs Wellcome inventors had conceived of the invention before they learned the results of the Phase I trials. For conception, we look not to whether one skilled in the art could have thought of the invention, but whether the alleged inventors actually had in their minds the required definite and permanent idea. *Cf. Bosies v. Benedict*, 27 F.3d 539, 543, 30 USPQ2d 1862, 1865 (Fed.Cir.1994) (testimony of noninventor as to noninventor's understanding of inventor's written formula insufficient to prove conception). The record does not now support resolution of this question as a matter of law.

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[8] We must assume for the purposes of this case that the '750 patent is drawn to an invention different from each of the other five patents. The parties do not ask us to decide whether claims drawn to an effect or mechanism of action of AZT—its ability to raise T-cell count—reach the same invention as (that is, are inherent in) claims drawn to use of the drug to treat HIV infection or AIDS, and we express no opinion on that. The dissent therefore goes beyond the issues presented and the record before us to decide on the basis of what the dissenting judge thinks he knows. That is not the role of an appellate court.

The alleged conception is supported by testimony of Burroughs Wellcome's experts, Burroughs Wellcome's draft Phase I protocol, and the same draft patent application that corroborates conception of the other five inventions. The experts testified that those skilled in the art at the time expected increased immune function to accompany inhibition of HIV. The draft patent application discloses that HIV preferentially destroys T-cells, that AIDS is associated with progressive depletion of T-cells, and that AZT is an effective treatment for HIV infection. Finally, the draft protocol directs the administrators of the Phase I study to monitor patients' T-lymphocyte count. This evidence supports an inference that the Burroughs Wellcome inventors did have the necessary definite and permanent idea, for, given the virus' effect on T-lymphocytes, it seems logical to conclude that stopping the virus might reverse the process of T-cell destruction and restore the body's immune system to a pre-infection state. If this were the only evidence in the record, the court's judgment would be sustained.

But Novopharm offered evidence suggesting that one skilled in the art would not have expected T-cell count to rise. On deposition, Broder testified that prior to the first patient study, "no one knew whether there was such a thing as recovery" of T-cells, based on the NIH's experience with suramin, a drug that entered clinical trials before AZT. Although suramin showed some activity against HIV, inhibition of the retrovirus apparently was not accompanied by increases in T-cell count or restoration of immune functions. Of course, there might be any number of other explanations for the results of the suramin trials; but they might suggest that although those skilled in the art recognized the significance of T-lymphocyte levels in HIV infection and AIDS, they might have expected inhibition of the virus simply to halt the continuing destruction of T-cells, not to increase T-cell count and restore immune function. This could support

an inference that the inventors themselves did not conceive the invention prior to the Phase I study.

Novopharm also contends that Burroughs Wellcome prepared its Phase I protocol in collaboration with Broder and the NIH, possibly from a draft protocol prepared by Broder and Yarchoan pursuant to their study of suramin. These contentions are relevant to the conception inquiry for they tend to undermine the corroborative value of the draft protocol, and might even support joint inventorship based on that draft. *See Coleman v. Dines,* 754 F.2d at 360, 224 USPQ at 863 (document's co-author cannot be considered sole inventor of invention disclosed in document without further proof). Because under Rule 50(a) all inferences must be taken against the moving party, the court's ruling on the '750 patent was inappropriate, and we vacate the judgment to that extent and remand for further proceedings.

Conclusion

Accordingly, the judgment of the United States District Court for the Eastern District of North Carolina is affirmed in part, vacated in part, and remanded.

LOURIE, Circuit Judge, concurring-in-part and dissenting-in-part.

I concur in the majority's decision with respect to the '232, '838, '130, '208, and '538 patents, and join the opinion except for the following:

I do not agree that reduction to practice is corroboration of conception and that the completeness of a conception is affected by subsequent experimental success or failure. These statements confuse the idea of conception with both corroboration and reduction to practice. A conception must be judged as to its completeness in relation to the invention being claimed. It must also be corroborated by evidence independent of the inventor. If subsequent experimentation shows that an invention that was only conceived does not work, that fact does not vitiate the earlier conception. A conception not later reduced to practice may have little significance, but it is important that we not confuse concepts. The conception was still a conception. It is of course possible for an invention to be reduced to practice constructively, *i.e.*, by filing a patent application, rather than actually, by doing the work, in which case the reduction to practice clearly says nothing about the completeness of the conception. Moreover, what matters, in addition to the completeness of a conception, is its date. Corroboration must be of the date of the conception. If the only "corroboration" of the conception is its reduction to practice, corroboration has not occurred concerning the alleged date of conception. Finally on this point, reduction to practice by the inventor is not corroboration because corroboration must be independent of the inventor. Corroboration is not a demonstration that the conceived invention works; it is evidentiary proof that the mental act of invention occurred on a certain date.

I also believe that the issue of joint inventorship is irrelevant here and therefore confusing. If the Burroughs Wellcome inventors had a complete conception, as we

hold, then the NIH scientists were not inventors because the invention had already been made, not because of any shortcomings in their inventive contributions. Thus, there is no need to discuss joint inventorship at all.

I respectfully dissent from the vacating of the court's judgment concerning the '750 patent. I believe that the method of the '750 patent is an inherent, inevitable result of the practice of the other method patents claiming treatment of HIV or AIDS. It seems to be the (or a) mechanism by which the other methods find their use.

Even if it is true that the first vertification or articulation of the increase in the T-cell count occurred in the hands of NIH scientists, this finding inures to the benefit of those who conceived the method of treatment that led to it. The method of the '750 patent is merely a refined definition of the method of the '232 patent, which issued from the original application. The '130 and '208 patents, which also came from applications later filed with the '750 and the composition patents, are also modifications of the original filing. It is common practice for applicants to claim all aspects of their invention and that is what appears to have happened here. An inventor is entitled to the inherent benefits that flow from his or her invention. It is improper to split the inventorship of what is one invention merely because the means by which it was achieved was later verified by scientists acting pursuant to the original conceivers.

The PTO of course issued these patents. During its examination, it determined that the '750 method was obvious over the '232 method. Given a terminal disclaimer, this led to the grant of the patent. More than being obvious, however, the method was inherent in the '232 method and therefore lacking in novelty. *See* 35 U.S.C. § 102 (1988). If, as I believe, the '750 invention does lack novelty over the other patents, its validity may be in question on the ground of double patenting because a terminal disclaimer is not effective to cure a double patenting prob-

lem when the inventions are the same. As long as the inventive entities are also the same, however, it doesn't really matter.

Even assuming that the '750 method is a separate invention, the majority concedes that evidence supports an inference that the Burroughs Wellcome inventors alone conceived the method. The majority goes off the track, however, in relying on Novopharm's offer of evidence that one would not have expected the T-cell count to rise. This is irrelevant if Burroughs Wellcome's inventors had the conception, because the opinion earlier correctly holds that a reasonable expectation of success is not necessary to a conception.

The majority here is inviting the trial court on remand and motion, *see* 35 U.S.C. § 256 (1988), to partially split the inventorship, and presumably also the ownership, of this related collection of patents claiming the physical act of "treating" and the result which the treatment accomplishes. This makes no sense. It amounts to deciding that treating a person in pain with aspirin is one invention and invoking the pain-relieving mechanism by means of that treatment is another. One cannot apparently treat HIV-infected humans with AZT without also increasing the level of T-lymphocytes. The panel is thus inconsistent in upholding the conclusion of the trial court that Burroughs Wellcome's scientists alone conceived the invention of using AZT to treat HIV infections, but then failing to arrive at the same conclusion regarding a patent claiming one of the sequelae of that use.

The real result of the majority's vacating the court's decision on the '750 patent is that, while it may believe that it is affirming the decision on the other patents, it may in practical effect be destroying Burroughs Wellcome's exclusivity for its invention and creating a whole new set of questions. If the trial court joins the NIH inventors, and NIH has licensed the patent to companies intending to sell AZT, will those companies infringe the

'232 and other patents? Is the terminal disclaimer still valid, lacking the consent of one of the assignees? Without a valid terminal disclaimer, is the '750 patent valid? While these questions are not before us, exploring them illustrates the strange consequences of the majority's decision. One the other hand, if the trial court confirms its finding that the T-lymphocyte "invention" was essentially the same invention and inured to the benefit of Burroughs Wellcome, the remand will have been superfluous. Useless and inefficient litigation and burdening of the courts will have resulted.

The trial court's decision should be affirmed across the board because it correctly found that the Burroughs Wellcome inventors solely conceived and are entitled to the inventive benefit of all the claimed inventions.

APPENDIX B

UNITED STATES DISTRICT COURT
E.D. NORTH CAROLINA
NEW BERN DIVISION

Nos. 91-41-CIV-4-H, 92-134-CIV-4-H,
and 92-156-CIV-4-H

BURROUGHS WELLCOME CO.,
Plaintiff,

v.

BARR LABORATORIES, INC.,
Defendant.

BURROUGHS WELLCOME CO.,
Plaintiff,

v.

NOVOPHARM, INC.,
Defendant.

BURROUGHS WELLCOME CO.,
Plaintiff,

v.

NOVOPHARM LTD.,
Defendant.

July 22, 1993

ORDER GRANTING JUDGMENT AS A MATTER OF LAW IN FAVOR OF PLAINTIFF BURROUGHS WELLCOME CO.

MALCOLM J. HOWARD, District Judge.

This matter is before the court on the plaintiff's motion for judgment as a matter of law filed June 30, 1993, and the plaintiff's renewed motion for judgment as a matter of law filed July 5, 1993. Also pending in this matter is the plaintiff's renewed motion for summary judgment filed June 18, 1993.

In the twenty-five months transpiring between the filing of the initial complaint in this consolidated patent infringement action on May 14, 1991, and the commencement of the trial on June 28, 1993, approximately five hundred forty-one pleadings have been filed and dozens of hearings on motions and discovery matters have been conducted by the court. The court has entered eighty-eight written orders and numerous bench rulings. Thus, the court is intimately familiar with the facts of this case and the legal contentions of the parties.

To state that the case has been hotly contested would be an understatement. The parties have amassed learned, experienced and sizable trial teams who have represented their clients zealously and competently.

The administrative complexity of conducting a trial of this magnitude has been enormous for the court and the parties. The sixty-year-old courtroom in New Bern, North Carolina, has been converted into a contemporary "high tech" facility utilizing "real time" court reporting and six computer-integrated video display monitors. It is highly conceivable that the cost of this trial for the parties exceeds $100,000 per day, in addition to the time and expense associated with this court and the jury. As this case enters its fourth week of trial, the parties estimate, somewhat conservatively the court suspects, that the trial will last an additional six to eight weeks.

With this preamble, the court will state briefly a synopsis of the procedural and factual background of the case. A more detailed statement of the procedural and factual background of the case can be found in the court's order dated June 3, 1993, denying plaintiff's motions for partial summary judgment. 828 F.Supp. 1200.

PROCEDURAL BACKGROUND

Plaintiff Burroughs Wellcome Co., ("BW Co."), a research-oriented pharmaceutical company, owns and controls six United States patents covering various methods of using azidothymidine ("AZT") in the treatment of persons infected with the Human Immunodeficiency Virus ("HIV"). BW Co. manufactures and sells AZT under the brand name Retrovir. At issue in this case is the proper naming of inventors on the following six patents owned by BW Co.: 1) U.S. Patent No. 4,724,232, filed September 17, 1985, issued February 9, 1988; 2) U.S. Patent No. 4,828,838, filed October 21, 1987, issued May 9, 1989; 3) U.S. Patent No. 4,833,130, filed October 20, 1987, issued May 23, 1989; 4) U.S. Patent No. 4,837,208, filed October 20, 1987, issued June 6, 1989; 5) U.S. Patent No. 4,818,538, filed October 21, 1987, issued April 4, 1989; and 6) U.S. Patent No. 4,818,750, filed October 20, 1987, issued April 4, 1989. The court will refer to these patents collectively as "the BW Co. patents."

Defendants Barr and Novopharm Ltd. filed Abbreviated New Drug Applications ("ANDA") with the Food and Drug Administration ("FDA") on March 19, 1991, and June 26, 1992, respectively, seeking approval to manufacture and distribute a generic equivalent of Retrovir. Both Barr and Novopharm Ltd. certified to the FDA, pursuant to 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e), that the BW Co. patents were either invalid or not infringed by the filing of their ANDAs. Barr asserted noninfringement for the reason, *inter alia*, that

two scientists employed by the National Institutes of Health ("the NIH"), Dr. Samuel Broder and Dr. Hiroaka Mitsuya, were coinventors of the subject matter claimed in the six BW Co. patents but had not been named as inventors on the patents. Because Barr received a nonexclusive license from the NIH to exploit any patent rights the NIH, as the employer of Dr. Broder and Dr. Mitsuya, might have in the BW Co. patents, Barr alleged that its ANDA was not an act of infringement.

Similarly, Novopharm Ltd. asserted that Dr. Broder and Dr. Mitsuya were coinventors of the subject matter claimed in the BW Co. patents, but in support of its contention that the BW Co. patents were invalid. Novopharm Ltd. contended that BW Co. omitted Dr. Broder and Dr. Mitsuya from the BW Co. patents with the intent to deceive the patent office and thereby engaged in inequitable conduct before the patent office. Novopharm Ltd. asserted that this alleged inequitable conduct invalidated the BW Co. patents.

STATEMENT OF FACTS

The BW Co. patents name the following five scientists employed by BW Co. as inventors: Dr. Janet Rideout; Dr. David Barry; Dr. Sandra Lehrman; Ms. Martha St. Clair; and Dr. Phillip Furman (collectively referred to as "the BW Co. inventors"). BW Co. is a world leader in antiviral therapy and experienced in retroviruses. BW Co. has been a leader in all aspects of the development of nucleoside analogs, particularly in their use as effective antiviral compounds.

The BW Co. inventors first began screening compounds for potential use as an AIDS therapy in 1984. In mid-1984, when the scientific community learned that AIDS was caused by a retrovirus, now referred to as HIV, the BW Co. inventors, specifically Ms. St. Clair,

began screening compounds for antiretroviral activity against two murine retroviruses.[1]

On October 29, 1984, Dr. Rideout selected AZT, identified as BW Co. compound 509U81, for testing in the murine screens. Ms. St. Clair tested AZT in the murine screens and reported that AZT showed significant activity against FLV and HaSV at low concentrations. After obtaining these positive results, the BW Co. inventors met on December 5, 1984, to discuss patenting the use of AZT to treat patients infected with HIV. After subsequent meetings held in early January 1985, the BW Co. patent committee recommended that a patent application covering the use of AZT as an AIDS therapy be prepared for future filing.

On February 4, 1985, BW Co. sent a sample of AZT under the code name Compound S to Dr. Broder at the NIH for screening against HIV in human cells. In the letter accompanying the sample, Dr. Lehrman informed Dr. Broder that Compound S had been tested in murine and feline leukemia virus systems and that preliminary data was available showing that HIV replication had been inhibited at certain concentrations. Dr. Lehrman suggested that Dr. Broder screen Compound S at concentrations of 1, 5, 10, and 50 micromolars.

By February 6, 1985, a draft patent application for filing in the United Kingdom was prepared by BW Co. employees and its patent agents and attorneys. This draft application did not name the inventors, but it disclosed how to make various pharmaceutical formulations of AZT in an effective dosage range for the purpose of treating HIV infections in humans. The dosage ranges disclosed in the draft patent application encompassed the recommended dosage ranges approved by the FDA

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[1] The two murine retroviruses used by BW Co. for testing were the Friend leukemia virus ("FLV") and the Harvey sarcoma virus ("HaSV").

in 1987. Based upon the information contained in the draft patent application, three expert witnesses on behalf of BW Co.[2] and one expert witness designated by Barr [3] stated in depositions that the draft patent application teaches one of ordinary skill in the art how to use AZT to treat patients infected with HIV. The draft patent application was reduced to final form and filed in the United Kingdom on March 16, 1985.

Dr. Mitsuya tested Compound S against HIV in human cells in mid-February 1985. His tests demonstrated that Compound S was active against HIV. On February 20, 1985, Dr. Broder phoned Dr. Lehrman to report the results of Dr. Mitsuya's testing.

DISCUSSION

Rule 50(a) of the Federal Rules of Civil Procedure provides that a court may grant judgment as a matter of law during a jury trial when, after a party has been fully heard on the issue, "there is no legally sufficient evidentiary basis for a reasonable jury" to find in favor of that party on that issue. In ruling on a Rule 50(a) motion, the court must consider all of the evidence in the light most favorable to the nonmoving party and determine "whether reasonable triers of fact could draw only one conclusion." *Bond v. Morton Buildings, Inc.*, 815 F.Supp. 944, 945 (S.D.W.Va.1993). To avoid judgment as a matter of law, the nonmoving party must come forward with more than a scintilla of evidence to support the material aspects of his case. *Id.; see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250-52, 106 S.Ct. 2505, 2511-12, 91 L.Ed.2d 202 (1986).

Under Rule 56, summary judgment is proper where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any ma-

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[2] Dr. Katz, Dr. White, and Dr. Whitley.

[3] Dr. Levine.

terial fact and that the moving party is entitled to a judgment as a matter of law." The standard for summary judgment under Rule 56 is very similar to the standard for judgment as a matter of law under Rule 50(a).

Inventorship

The above facts are found by the court to be fully supported by the record. The parties and the court agree that the only real dispute in this case is the appropriate legal standard that will apply to these facts. The parties candidly represent to the court that the resolution of the appropriate legal standard is outcome determinative.

In previous rulings, the court has defined conception as the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice. The court refused to adopt the legal standard asserted by the defendants in response to BW Co.'s motion for partial summary judgment that an inventor must have a "reasonable basis" for believing that an invention will work before conception can be complete.

The law of conception as understood by the court is comprised of two elements. The first element relates to the state of mind of the inventor—whether he had a definite and permanent idea of the complete and operative invention. This element is subjective; so long as the idea is sufficiently defined and preserved, the law does not require that the inventor's idea be reasonable, scientifically accurate, or capable of being proved. This legal definition of the first element of conception is the object of the parties' current dispute and permeates the whole of the defendants' case.

The second element asks whether the inventor's idea, as defined and preserved, enables one of ordinary skill in the art to reduce the invention to practice. This ele-

ment is objective. The parties have no quarrel with the court's definition of the second element.

Defendant Barr has argued that the definition of conception requires that the BW Co. inventors must have a definite and permanent idea that AZT would be effective in treating humans suffering from AIDS. Barr contends that it must be permitted to introduce evidence that challenges and undermines the murine screen used by the BW Co. inventors as a basis for their claimed definite and permanent idea that AZT would be effective in treating humans suffering from AIDS. Counsel for Barr has candidly stated that the heart of its case rests on the admissibility of evidence regarding the predictiveness, or lack thereof, of murine screens in forming the idea that AZT would be active against a human retrovirus.

In contrast, BW Co. contends that the phrase "definite and permanent" in the context of conception relates to the inventor's ability to describe and preserve his idea and *not* to the inventor's belief that the idea will actually work.

The court agrees with BW Co.'s contention regarding the definition of conception. The court does not believe that the phrase "definite and permanent idea" requires that the BW Co. inventors *know* that AZT would be effective in treating humans having AIDS. For conception to be complete, the law does not require an idea to be proven to actually work. The defendants candidly admitted that their case depends upon the evidence concerning the reliability or predictiveness of the murine screens used by the BW Co. inventors, which this court determines has no legal relevance.

In light of the candid representations of defendants' counsel that they would be unable to satisfy their burden of proof by clear and convincing evidence under the court's definition of the first element of conception, the

court informed the defendants that it would consider BW Co.'s motions for judgment as a matter of law pursuant to Fed.R.Civ.P. 50(a). With this notification, counsel for the defendants presented written offers of proof and were given additional time to further supplement their offers of proof. The court has very carefully reviewed the defendants' written offers of proof and supplemental offers of proof and afforded them an opportunity to be heard orally.

Having given the defendants the opportunity to be fully heard, the court will set forth its findings and conclusions in light of the legal definition of conception adopted by the court. Reviewing all of the evidence and resolving all inferences in favor of the defendants, the court finds no evidence which would enable the defendants to meet their burden of proof in this case. The pleadings in the case and the evidence presented in three weeks of trial testimony satisfy the court without doubt that no legally sufficient evidentiary basis exists for a reasonable jury to find that the BW Co. inventors did not have a complete conception of the invention independent of the testing performed by Dr. Broder and Dr. Mitsuya. The admissible evidence clearly establishes, and this court finds as a matter of law, that the BW Co. inventors formed a definite and permanent idea of using AZT as a therapy for AIDS without any inventive contribution from Dr. Broder and/or Dr. Mitsuya.

Furthermore, in light of all of the evidence, the court concludes that the BW Co. inventors' idea was sufficiently described to allow one of ordinary skill in the art to practice the invention. The evidence in the record shows that the draft patent application was sufficient to enable one of ordinary skill in the art to practice the invention, that is, to treat a patient infected with HIV with an effective dosage amount of AZT. Thus, the evidence fully satisfies the second element of conception.

In reaching its legal conclusions on the elements of conception, the court has relied upon the holdings in such cases as *Hybritech, Inc. v. Monoclonal Antibodies*, 802 F.2d 1367 (Fed.Cir.1986), *Rey-Bellet v. Engelhardt*, 493 F.2d 1380 (C.C.P.A.1974), *MacMillan v. Moffett*, 432 F.2d 1237 (C.C.P.A.1970), and *Applegate v. Scherer*, 332 F.2d 571 (C.C.P.A.1964). The court notes further that a party who conducts tests wholly at the direction and instruction of another is merely a technician and not a conceiver and acts merely as a "pair of hands." The court finds that this last statement accurately characterizes the role played by Dr. Broder and Dr. Mitsuya. The evidence in the record shows that BW Co. sent Compound S to the NIH with specific instructions and directed the testing performed by Dr. Broder and Dr. Mitsuya.

Accordingly, the court concludes that BW Co. is entitled to judgment as a matter of law. The court finds that the evidence in this case is overwhelming and conclusive that the BW Co. inventors, and only the BW Co. inventors, first conceived of the idea of using AZT as a therapy for treating persons infected with HIV. Their definite and permanent idea was expressed in such documents as the February 6, 1985, draft patent application and the February 4, 1985, letter from Dr. Lehrman to Dr. Broder. In addition, the court has heard and considered the testimony of the inventors regarding their formation of the idea that AZT would be an effective AIDS therapy.

The court also finds that the evidence is equally strong in relation to U.S. Patent No. 4,818,750 claiming the use of AZT to increase a patient's T-lymphocyte count. Novopharm Ltd. and Novopharm, Inc., contend that there is no evidence that the BW Co. inventors thought of this use until Dr. Broder and Dr. Yarchoan reported these results following the administration of AZT to a human during clinical trials. However, the court has

heard substantial testimony that an increase in the T-lymphocyte count was an "obvious," natural phenomenon known to the BW Co. inventors that would result from the inhibition of a retrovirus.

Estoppel

Defendant Barr has also renewed its motion for partial summary judgment on the issue of estoppel, laches, and waiver. The court previously denied Barr's motion for partial summary judgment on these issues following oral argument on June 14, 1993. The court found that certain factual determinations precluded the entry of summary judgment.

Barr's primary contention in support of its motion is that the Property Clause of the United States Constitution holds that the government cannot be denied property rights through the assertion of the equitable doctrines of estoppel, laches, and waiver. Under the Property Clause and the cases applying it, government property may be disposed of only as authorized by Congress and government officials without proper authority cannot cause the government to lose its property rights. *See California v. United States*, 457 U.S. 273, 102 S.Ct. 2432, 73 L.Ed.2d 1 (1982); *United States v. California*, 332 U.S. 19, 67 S.Ct. 1658, 91 L.Ed. 1889 (1947). Barr alleges that the government has never authorized the disposal of its patent rights through estoppel, laches, or waiver, and, therefore, these equitable defenses must be dismissed as a matter of law.

The court is not persuaded that the Property Clause is implicated in this action. Although a patent right is a property right, the rights being asserted by Barr in this case have not yet ripened into "property." The patent right being asserted[4] by Barr on behalf of the govern-

[4] The court questions whether the government is, in fact, asserting any rights or taking any action to protect its rights in this

ment in this action is the government's alleged ownership interest in the BW Co. patents.

Barr asserted in its previous motion for partial summary judgment on this issue that ownership rights in a patent inure *automatically* to the government. For the reasons stated below, the court disagrees with Barr's application and interpretation of this statement.

"At the heart of any ownership analysis lies the question of who first invented the subject matter at issue, *because the patent right initially vests in the inventor* who may then, barring any restrictions to the contrary, transfer that right to another, and so forth." *Beech Aircraft Corp. v. EDO Corp.*, 990 F.2d 1237, 1248 (Fed.Cir. 1993) (emphasis added). Only natural persons can be inventors. *Id.* at 1248 n. 2. Because the government is not a natural person, the government cannot be an inventor. Therefore, patent rights cannot vest *automatically* in the government. The government must derive patent rights from an inventor.

In this case, the inventors from whom the government claims an ownership interest are Drs. Broder and Mitsuya. In order for the government to acquire an ownership interest in the BW Co. patents through Drs. Broder and Mitsuya, two conditions must be satisfied. First, Drs. Broder and Mitsuya must be inventors of the BW Co. patents. Second, Drs. Broder and Mitsuya must transfer, by assignment or otherwise, their ownership rights to the government.

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litigation. It is not a party to this proceeding, and it has repeatedly reminded the court that it is not a party to this proceeding. It participated very begrudgingly in discovery, which became the subject of numerous motions to compel culminating in an on-site inspection of the files of the NIH attended by this court. The only action taken by the government to preserve its alleged rights was the negotiation of a licensing agreement with the defendant Barr which obligated Barr to represent the government's interest in this action.

Putting aside the first condition, the court finds that the government is not able to establish the second condition in order to support the contention that the government *has* an ownership interest to protect. Although a formal assignment is not necessary in order for the government to obtain ownership rights in the inventions of its employees, *see* Executive Order 10096; *In re Williams*, 228 U.S.P.Q. 381 (Comm'r Pat.1985), federal regulations provide the proper procedures to be followed when a government employee seeks to establish patent rights. *See* 37 C.F.R. § 100.6(c)(3).

The record is devoid of any evidence showing that Dr. Broder and/or Dr. Mitsuya ever filed or submitted an employee invention report identifying themselves as coinventors of the subject matter of the BW Co. patents. In fact, the court has found no evidence showing that Dr. Broder and/or Dr. Mitsuya ever took *any* action to establish their status as coinventors. Therefore, the court finds no basis for finding that the government has a constitutionally-protected property interest in the BW Co. patents.

Accordingly, the court DENIES Barr's renewed motion for partial summary judgment on the issue of estoppel, latches, and waiver. Whether these equitable doctrines can be applied in this case is a question that cannot be decided as a matter of law. This ruling in no way expresses any opinion as to whether the elements of these doctrines can be satisfied in this case based upon the evidence.

CONCLUSION

For the foregoing reasons, the court hereby GRANTS BW Co.'s motion for judgment as a matter of law pursuant to Fed.R.Civ.P. 50(a)(1). The court finds that the BW Co. inventors had a complete conception, that is, they had a definite and permanent idea of a complete and operative invention as it was thereafter to be applied in practice, independent of any inventive contribution from Dr. Broder and Dr. Mitsuya. Having found that there is

no basis in law for the contention that Dr. Broder and Dr. Mitsuya are coinventors, the court concludes that Novopharm, Inc., and Novopharm Ltd.'s defense of inequitable conduct fail as a matter of law and are hereby DISMISSED.

All other pending motions are hereby DISMISSED.

Pursuant to Fed.R.Civ.P. 50(a), judgment shall forthwith be entered in favor of the plaintiff Burroughs Wellcome Co.

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Pfizer

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